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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,915	07/13/2006	Christopher Becker	100792-1P US	1090

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EXAMINER	
HOUGHTLING, RICHARD A	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
02/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,915	BECKER ET AL.	
	Examiner	Art Unit	
	RICHARD A. HOUGHTLING	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-5 and 7-10* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *17 July 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions, which are not so linked, as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-2 and 5	drawn to a method for treatment or prophylaxis of psychotic disorders, intellectual impairment disorders or conditions in which modulation of the alpha-7 nicotinic receptor is beneficial comprising administering a therapeutically effective amount of a compound of Formula I or Formula II, and classified in class 424, subclass 810.
Group II, claim 3	drawn to a pharmaceutical composition comprising a compound according to Formula I or Formula II, and classified in class 514, subclass, 290.
Group III, claim 4	drawn to a pharmaceutical composition comprising a compound according to Formula I or Formula II, and further comprising a nicotinic receptor agonist.
Group IV, claims 7-9	drawn to a compound of Formula I or II, and classified in class 540, subclass 519.

Group V, claim 10	drawn to a method of making a compound of Formula I or Formula II, and classified in class 514, subclass 290.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature in all groups is a compound of Formula I or Formula II.

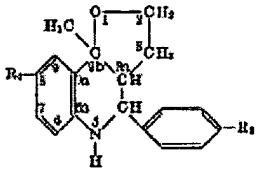
An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is permitted only if all, inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

The expression "special technical features" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any). Whether or not any particular technical feature makes a "contribution" over the

prior art, and therefore constitutes a "special technical feature," should be considered with respect to novelty and inventive step.

The common technical feature in all groups is a compound of Formula I or Formula II. This element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art.

In this case, Elslager et al. (U.S. Patent 3,631,050, as found in Applicants' IDS filed on 17 July 2006) teach a series of compounds represented by Applicants' Formula II. Elslager et al. teaches this compound,



(see col. 1, lines 30-40; and claim 1). Likewise in the pending application, Formula II as is found within claims 1-5 and 7-10 is a generic formula that encompasses the compound found in Elslager et al.

Since a compound, that meets the general features of Formula II, has been identified in the prior art, there is no special technical feature present in the claims. As a result, the inventions in Groups I-V fail to make a contribution over the prior art with respect to novelty and inventive step. In conclusion, there is a lack of unity of inventions, and therefore restriction for examination purposes as indicated is proper.

Furthermore, the claims encompass methods using hundreds of different compounds, which are contained in many different compositions. The compounds vary distinctly in their structures and functions. Thus, an individual search is required of each individual compound. Therefore, as part of electing one of the groups as the elected invention, Applicant is also required to elect a specific compound, to which the elected invention will be examined on the merits as drawn to (if the elected compound cannot be found, then the examiner will open the search up to a reasonable core structure); as well as, identify the claims to which the elected compound is drawn, including any claims subsequently added. This requirement is *not* to be taken as an election of species, but rather as an election of a single invention, since each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.

Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.141).

Should applicant traverse on the ground that the compounds are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1) a compound of Formula I or Formula II;

2) a disorder; and

3) a nicotinic receptor agonist.

Applicant is required, in reply to this action, to elect a single species of (1) a compound of Formula I or a compound of Formula II; (2) a disorder selected from psychotic disorders, intellectual impairment disorders or diseases or conditions in which modulation of the nicotinic receptor is beneficial, such as, a disorder found in claim 2; and (3) a specific compound which is a nicotinic receptor agonist to which the claims

shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3. The claims are deemed to correspond to the species listed above in the following manner: (1) Claims 1-5 and 6-10 are drawn to a method, pharmaceutical composition, a compound or process of making a compound of Formula I or Formula II; (2) Claims 1-2 and 5 are drawn to methods for treatment or prophylaxis of psychotic disorders, intellectual impairment disorders or diseases or conditions in which modulation of the alpha-7 nicotinic receptor is beneficial, which comprises administering an effective amount of a compound of Formula I or Formula II; and (3) Claims 4-5 are drawn to a pharmaceutical composition or a method for treatment using a pharmaceutical composition, which further comprises a nicotinic receptor agonist.

The following claim(s) are generic: 1) Claims 1-5 and 7-10; 2) Claims 1-2 and 5, in part; and 3) Claims 4-5, in part.

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Claims 1-5 and 7-10 are directed to compounds of Formula I or Formula II, of which each is structurally distinct.

If Group I is elected, the Applicant is required to elect: (1) a compound from Formula I or II; and if Formula II is elected, Applicant is further required to elect a species of X, which is O, S or CH_2; and (2) a disclosed species of psychotic disorder, intellectual impairment disorder or condition in which modulation of the alpha-7 nicotinic receptor is beneficial such as one from those found in the Specification (page 2, lines 4-8).

If Group II, IV or V is elected, the Applicant is required to elect: (1) compound from Formula I or II; and if Formula II is elected, Applicant is further required to elect a species of X, which is O, S or CH_2.

If Group III is elected, the applicant is required to elect: (1) compound from Formula I or II, and if Formula II is elected, Applicant is further required to elect a species of X, which is O, S or CH_2; and (3) a disclosed species of a nicotinic receptor agonist (see page 4, lines 5-13).

Applicant is advised that in order for the reply to this requirement to be complete it must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call to the attorney is not required where: 1) the restriction requirement is complex, 2) the application being prosecuted pro se, or 3) the examiner knows from past experience that a telephone election will not be made (MPEP § 812.01). Therefore, since this restriction is considered complex, a call to the attorney for telephone election was not made.

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard A. Houghtling, Ph.D. whose telephone number is 571-272-9334. The examiner can normally be reached Monday to Thursday from 8:00 am - 5:00 pm, and on alternate Fridays 8:00 AM - 12:00 Noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on 571-272-0623. The Group 1600 fax phone number where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Richard A. Houghtling, Ph.D.
Patent Examiner

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER